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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,214	12/01/2003	Muraleedharan G. Nair	MSU 4.1-672	4443

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/725,214	<b>Applicant(s)</b> NAIR ET AL.	
	<b>Examiner</b> Michele Flood	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 01 December 2003.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-5 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
       Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
       a) ☐ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
       Paper No(s)/Mail Date 12/03.

4) ☐ Interview Summary (PTO-413)  
       Paper No(s)/Mail Date. \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation “the compounds” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Although not rising to the level of uncertainty, with regard to Claim 1, lines 3-4, the phrase “providing with the cells an effective amount of anthocyanin” renders the claim somewhat unclear. Applicant should delete “with” to provide clarity to the claim language.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kamei et al. (U).

Applicant claims a method for the inhibition of proliferation of cancer cells of the stomach or colon which comprises: providing the cells with an effective amount of anthocyanidin selected from the group consisting of cyanidin, delphinidin, malvidin, pelargonidin, petunidin and mixtures thereof, to inhibit the proliferation of the cells.

Kamei teaches a method for the inhibition of the proliferation of HCT-15 cells, derived from human colon cancer or AGS cells, derived from human gastric cancer, comprising administering to the cells an anthocyanin fraction from red wine. Kamei further teaches, "Thin-layer chromatographic analysis revealed mostly delphinidin in the anthocyanin fraction.

The reference anticipates the claimed subject matter.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Koide et al. (V).

Applicant's claimed invention of Claim 1 was set forth above. Applicant further claims the method of claim 1, wherein the anthocyanidin is selected from the group consisting of malvidin and pelargonidin.

Koide teaches a method of inhibiting the proliferation of colon cancer cells comprising the administration of an effective amount of the anthocyanidins, cyanin, pelargonidin, and delphinidin, to HCT-15 cells.

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamei et al. (U) and Koide et al. (V) in view of Tsuda et al. (W).

Applicant's claimed invention of Claims 1 and 2 was set forth above. Applicant further claims the method of claim 2, wherein the cells are stomach tumor cells. Applicant further claims a method of claim 1 or claim 2, wherein the cells are in a mammal; and, wherein the cells are in a mammal and the anthocyanidin is fed orally to the mammal.

The teachings of each of Kamei and Koide are set forth above. The teachings of each of Kamei and Koide teach the instantly claimed invention except for wherein the

cells are stomach tumor cells; wherein the cells are in a mammal; and wherein the claim-designated compounds are fed orally to a mammal. However, it would have been obvious to one of ordinary skill in the art to provide the instantly claimed method for the inhibition of cancer cells of the stomach or colon comprising the oral administration of an effective amount of the claim-designated compounds to a mammal because at the time the invention was made Tsuda taught that the oral administration of an effective amount of an anthocyanin, such as cyanidin, to a mammal was absorbed and metabolized *in vivo*. On page 181, Column 2, lines 9-11, Tsuda also teaches that cyanidin (C3G) and its metabolites were detected in the stomach and jejunum of animals that received cyanidin by oral administration. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of providing the instantly claimed method of treatment because Kamei taught that administering effective amounts of delphinidin to either human colon cancer cells or stomach cancer cells inhibited proliferation of the cancer cells; Koide taught that administering effective amounts of the anthocyanidins, cyanin, pelargonidin, and delphinidin, to HCT-15 cells inhibited the proliferation of the human colon cancer cells; and, Tsuda suggests that the oral administration of effective amounts of anthocyanins to mammals in need thereof may provide a protective potency in reducing the risk of carcinogenesis. See "*Results and discussion*", on pages 181-182.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method of treatment are result variables, they would

Art Unit: 1654

have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 13-23 of U.S. Patent No. 6,656,914 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of the patent claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

Application/Control Number: 10/725,214

Page 7

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Michele C. Flood*

**MICHELE FLOOD**  
**PATENT EXAMINER**

MCF

January 24, 2005